



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.usplo.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|---------------|----------------------|-------------------------|------------------|
| 10/005,577 | 12/03/2001 | Steven M. Lefkowitz | 10980852-1 | 8145 |
| 75 | 90 06/17/2004 | | EXAM | INER |
| AGILENT TECHNOLOGIES, INC. | | | FORMAN, BETTY J | |
| Legal Department, DL429 Intellectual Property Administration | | | ART UNIT | PAPER NUMBER |
| P.O. Box 7599 | | | 1634 | |
| Loveland, CO | 80537-0599 | | DATE MAILED: 06/17/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | |
|---|--|--|--|--|
| | 10/005,577 | LEFKOWITZ ET AL. | | |
| Office Action Summary | Examiner | Art Unit | | |
| | BJ Forman | 1634 | | |
| The MAILING DATE of this communication Period for Reply | n appears on the cover sheet w | ith the correspondence address | | |
| A SHORTENED STATUTORY PERIOD FOR R THE MAILING DATE OF THIS COMMUNICATI - Extensions of time may be available under the provisions of 37 C after SIX (6) MONTHS from the mailing date of this communicatic - If the period for reply specified above is less than thirty (30) days, - If NO period for reply is specified above, the maximum statutory p - Failure to reply within the set or extended period for reply will, by Any reply received by the Office later than three months after the earned patent term adjustment. See 37 CFR 1.704(b). | ON. FR 1.136(a). In no event, however, may a on. , a reply within the statutory minimum of thin period will apply and will expire SIX (6) MON statute, cause the application to become A | reply be timely filed rty (30) days will be considered timely. NTHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133). | | |
| Status | | | | |
| 1) Responsive to communication(s) filed on | <u>05 March 2004</u> . | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ | This action is non-final. | | | |
| 3) Since this application is in condition for all | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is | | | |
| closed in accordance with the practice un | der <i>Ex parte Quayle</i> , 1935 C.[|). 11, 453 O.G. 213. | | |
| Disposition of Claims | | | | |
| 4)⊠ Claim(s) <u>31,33-40 and 42-52</u> is/are pendir | ng in the application. | | | |
| 4a) Of the above claim(s) is/are with | hdrawn from consideration. | | | |
| 5) Claim(s) is/are allowed. | | | | |
| 6)⊠ Claim(s) <u>31,33-40 and 42-52</u> is/are rejected | ed. | | | |
| 7) Claim(s) is/are objected to. | | | | |
| 8) Claim(s) are subject to restriction a | ind/or election requirement. | | | |
| Application Papers | | | | |
| 9) The specification is objected to by the Exa | | | | |
| 10) The drawing(s) filed on is/are: a) ☐ | | • | | |
| Applicant may not request that any objection to | • , , | ` ' | | |
| Replacement drawing sheet(s) including the co | , | .,, | | |
| 11) The oath or declaration is objected to by the | ne Examiner. Note the attached | d Office Action or form PTO-152. | | |
| Priority under 35 U.S.C. § 119 | | | | |
| 12) Acknowledgment is made of a claim for for | reign priority under 35 U.S.C. { | § 119(a)-(d) or (f). | | |
| a) ☐ All b) ☐ Some * c) ☐ None of: | | | | |
| 1. Certified copies of the priority docur | | | | |
| 2. Certified copies of the priority docur | | | | |
| 3.1 Copies of the certified copies of the | priority documents have been | received in this National Stage | | |
| application from the International Bu | | | | |

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.

4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.

5) Notice of Informal Patent Application (PTO-152)
6) Other: ____.

Art Unit: 1634

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5 March 2004 has been entered.

Status of the Claims

2. This action is in response to papers filed 5 March 2004 in which claims 31 and 40 were amended, claims 1-30, 32 and 41 were canceled and claims 49-52 were added. All of the amendments have been thoroughly reviewed and entered.

The previous rejections in the Office Action dated 5 December 2003, not reiterated below, are withdrawn in view of the amendments. All of the arguments have been thoroughly reviewed and are discussed below as they apply to the instant ground for rejection. New grounds for rejection are discussed.

Claims 31, 33-40, 42-52 are under prosecution.

Art Unit: 1634

Claim Rejections - 35 USC § 112

35 U.S.C. 112: First Paragraph

- 3. The following is a quotation of the first paragraph of 35 U.S.C. 112:
 - The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
- 4. Claims 49-52 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The recitation "homogeneous mixture of vinyl monomers" is added to the new Claim 49 from which Claims 50-52 depend. Applicant points to pages 12 and 15 for support for the newly added limitations. However, the cited passages do not teach or describe the claimed homogeneous mixture". A review of the entire specification did not reveal the required support. Hence, the specification fails to define or provide any disclosure to support such claim recitation.

MPEP 2163.06 notes "IF NEW MATTER IS ADDED TO THE CLAIMS, THE EXAMINER SHOULD REJECT THE CLAIMS UNDER 35 U.S.C. 112, FIRST PARAGRAPH - WRITTEN DESCRIPTION REQUIREMENT. IN RE RASMUSSEN, 650 F.2D 1212, 211 USPQ 323 (CCPA 1981)." MPEP 2163.02 teaches that "Whenever the issue arises, the fundamental factual inquiry is whether a claim defines an invention that is clearly conveyed to those skilled in the art at the time the application was filed...If a claim is amended to include subject matter, limitations, or terminology not present in the application as filed, involving a departure from, addition to, or deletion from the disclosure of the application as filed, the examiner should conclude that the claimed subject matter is not described in that application." MPEP 2163.06 further notes "When an amendment is filed in Reply to an objection or rejection based on 35 U.S.C. 112, first paragraph, a study of the entire application is often necessary to determine whether or not "new matter" is involved. Applicant should therefore specifically point out the support for any amendments made to the disclosure" (emphasis added).

Page 4

Application/Control Number: 10/005,577

Art Unit: 1634

35 U.S.C. 112: First Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 43 and 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 43 is indefinite for the recitation "said polymer backbone" because the recitation lacks proper antecedent basis in Claim 40.

Claim 48 is indefinite for the recitation "an additional non-nucleotidic polymer" because the recitation lacks proper antecedent basis in Claim 40.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application

Art Unit: 1634

designated the United States and was published under Article 21(2) of such treaty in the English language.

8. Claims 31, 33-40, 42-50 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Klaerner et al. (U.S. Patent Application Publication No. 2002/0001845, filed 24 July 2001).

Regarding Claim 31, Klaerner et al disclose a process for preparing a solid support comprising providing a solid support comprising a surface coating having a reactive site (e.g. surface hydroxyls ¶ 79 or initiator comprising hydroxyl, carboxyl, amino or thiol,, ¶ 73-76 and ¶ 92), contacting the surface coating with a plurality of monomers (¶ 124 and Example 1 & 2: ¶ 217 and 220), and polymerizing the monomers to produce a solid support having a surface tethered polymer covalently linked to the surface coating, said polymer having at least one adsorbing moiety for non-covalent attachment of a biomolecule (¶ 123, especially, lines 10-15).

Regarding Claim 33, Klaerner et al disclose the method wherein a portion of the biomolecule is an exogenous linking moiety (i.e. chemical hook, ¶ 138).

Regarding Claim 34, Klaerner et al disclose the method wherein the polymer is substantially linear (¶ 116, line 1).

Regarding Claim 35, Klaerner et al disclose the method wherein the polymer is a vinyl polymer (¶ 125-126).

Regarding Claim 36, Klaerner et al disclose the method wherein the adsorbing moiety is an amine group (¶ 123).

Regarding Claim 37, Klaerner et al disclose the method wherein the vinyl polymer is poly-vinylamine (i.e. vinyl imidazole, ¶ 126, next to last line).

Regarding Claim 38, Klaerner et al disclose the method wherein the biomolecule comprises an oligonucleotide or polynucleotide (¶ 135-138).

Regarding Claim 39, Klaerner et al disclose the method further comprising polymerizing additional non-nucleotidic polymer tethered to the surface coating said polymer comprising

Art Unit: 1634

additional adsorbing moieties (i.e. a plurality of polymers each attached to a biological probe, ¶ 28).

Regarding Claim 40, Klaerner et al disclose a process for preparing a solid support comprising providing a solid support comprising a surface coating having reactive sites (e.g. surface hydroxyls ¶ 79 or initiator comprising hydroxyl, carboxyl, amino or thiol, ¶ 73-76 and ¶ 92), contacting the surface coating with a plurality of monomers (¶ 124 and Example 1 & 2: ¶ 217 and 220), and polymerizing the monomers to produce a solid support having a surface tethered polymer covalently linked to the surface coating, said polymer having adsorbing sites for non-covalent attachment of a biomolecule (¶ 123, especially, lines 10-15) wherein the polymer is capable of assuming a plurality of conformations and exhibits sufficient mobility and flexibility such that the number of biomolecule adsorbed is maximized (¶ 31-32, 45-48) and contacting the surface with the probe biomolecules (Example 19: ¶ 262-263).

Regarding Claim 42, Klaerner et al disclose the method wherein a portion of the biomolecule is an exogenous linking moiety (i.e. chemical hook, ¶ 138).

Regarding Claim 43, Klaerner et al disclose the method wherein the polymer is substantially linear (¶ 116, line 1).

Regarding Claim 44, Klaerner et al disclose the method wherein the polymer is a vinyl polymer (¶ 125-126).

Regarding Claim 45, Klaerner et al disclose the method wherein the adsorbing moiety is an amine group (¶ 123).

Regarding Claim 46, Klaerner et al disclose the method wherein the vinyl polymer is poly-vinylamine (i.e. vinyl imidazole, ¶ 126, next to last line).

Regarding Claim 47, Klaerner et al disclose the method wherein the biomolecule comprises an oligonucleotide or polynucleotide (¶ 135-138).

Regarding Claim 48, Klaerner et al disclose the method further comprising polymerizing additional non-nucleotidic polymer tethered to the surface coating said polymer comprising

Art Unit: 1634

additional adsorbing moieties (i.e. a plurality of polymers each attached to a biological probe, ¶ 28).

Regarding Claim 49, Klaerner et al disclose a process for preparing a solid support comprising providing a solid support comprising a surface coating having a reactive site (e.g. surface hydroxyls ¶ 79 or initiator comprising hydroxyl, carboxyl, amino or thiol, ¶ 73-76 and ¶ 92), contacting the surface coating with a homogenous mixture of vinyl monomers (¶ 124-126 and Example 1 & 2: ¶ 217 and 220), and polymerizing the monomers to produce a solid support having a surface tethered polymer covalently linked to the surface coating, said polymer having at least one adsorbing moiety for non-covalent attachment of a biomolecule (¶ 123, especially, lines 10-15).

Regarding Claim 50, Klaerner et al disclose the process having a reactive site comprising hydroxyl, carboxyl, amino or thiol (¶ 73-76 and ¶ 92),

Regarding Claim 51, Klaerner et al disclose the method wherein the vinyl polymer is poly-vinylamine (i.e. vinyl imidazole, ¶ 126, next to last line).

Response to Arguments

9. Applicant argues that Klaerner does not teach surface reactive groups (i.e. hydroxyl, carboxyl, amino or thiol) as claimed. The argument has been considered but is not found persuasive because Klaerner specifically exemplifies hydroxyl reactive groups (¶ 79, lines 5-6 and Fig. 2). Applicant appears to be arguing that Klaerner does not contact the reactive groups with the monomers. However, the claims are not so limited. The claims merely require a solid support comprising a surface coating having a surface reactive group. While Klaerner further derivitize their surface with the initiator, the open claim language "comprising" and "having" recited in the instant claims encompasses the solid support and coating having hydroxyl groups as taught by Klaerner. Furthermore, Klaerner teach the initiator comprises a

Art Unit: 1634

surface reactive moiety "R" selected from hydroxyl, carboxyl, amino or thiol (¶ 92). Hence, Klaerner discloses the method as claimed.

Regarding new claim 50, Applicant argues that Klaerner fails to disclose a homogeneous mixture of vinyl monomers because they teach co-polymers comprising polyacrylamide-based-repeat units and hence do not teach non-acrylamide monomers. The argument has been considered but is not found persuasive because the claims are not limited to non-acrylamide monomers. Hence, the arguments are not commensurate in scope with the claims. The instant claims require "a homogenous mixture of vinyl monomers". The Ninth New Collegiate Dictionary "homogenous" as "same or similar nature or kind" and defines "mixture" as "matter consisting of two or more components in varying proportions". Klaerner teaches polymers are prepared from repeated units of acrylamide monomers and vinyl monomers (monomers) i.e. mixture as defined above. The mixture of Klaerner is deemed homogeneous because it consists of "repeat units" i.e. the same units.

The claims are given the broadest reasonable interpretation consistent with the indefinite claim language and specification wherein the newly claimed "homogenous mixture of vinyl monomers" is not defined. Given the broadest reasonable interpretation of the claims, Klaerner teaches the claimed invention.

The courts have stated that claims must be given their broadest reasonable interpretation consistent with the specification *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997); *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-551 (CCPA 1969); and *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989) (see MPEP 2111).

Art Unit: 1634

NEW GROUNDS FOR REJECTION

10. Claims 31, 33-34, 38, 40, 42-43 and 47 are rejected under 35 U.S.C. 102(b) as being Holmes by (ups 5,550,215, issued 27 August 1996).

Regarding Claim 31, Holmes discloses a process for preparing a solid support comprising providing a solid support with a surface coating having surface reactive hydroxyl, carboxyl, amino or thiol ("Y", Column 16, lines 23-25 and Column 19, lines 61-64), contacting the surface with a plurality of monomer and polymerizing the monomer to produce a support having surface tethered polymers covalently linked to the surface and having at least one adsorbing moiety e.g. hydroxyl and amine groups on amino acids (Claim 1).

Regarding Claim 33, Holmes discloses the process wherein the biomolecule is a linking molecule (Column 4, lines 57-67).

Regarding Claim 34, Holmes discloses the process wherein the polymer is substantially linear (Column 4, lines 60 and Fig. 1-2)

Regarding Claim 38, Holmes discloses the process wherein the biomolecules comprises an oligo or polynucleotide (Column 4, lines 60-61).

Regarding Claim 40, Holmes discloses a process for preparing a solid support comprising providing a solid support with a surface coating having surface reactive hydroxyl, carboxyl, amino or thiol ("Y", Column 16, lines 23-25 and Column 19, lines 61-64), contacting the surface with a plurality of monomer and polymerizing the monomer to produce a support having surface tethered polymers covalently linked to the surface and having at least one adsorbing moiety e.g. hydroxyl and amine groups on amino acids (Claim 1) and wherein the polymer is capable of assuming a plurality of conformations such that the number of biomolecules adsorbed is maximized (Fig. 1-2).

Regarding Claim 42, Holmes discloses the process wherein the biomolecule is a linking molecule (Column 4, lines 57-67).

Regarding Claim 43, Holmes discloses the process wherein the polymer is substantially

Page 10

linear (Column 4, lines 60 and Fig. 1-2)

Regarding Claim 47, Holmes discloses the process wherein the biomolecules comprises

an oligo or polynucleotide (Column 4, lines 60-61).

Regarding Claim 48, Holmes discloses the process further comprising polymerizing additional non-nucleotide polymers tethered to the surface e.g. SEQ ID NO: 10 & 11 (Column 26, lines 49-55).

Conclusion '

- 11. No claim is allowed.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BJ Forman whose telephone number is (571) 272-0741. The examiner can normally be reached on 6:00 TO 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BJ Forman, Ph.D. Primary Examiner Art Unit: 1634 June 16, 2004